

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Ream et al. ATTY DOCKET NO.: P99,0082
 SERIAL NO: 09/286,818 GROUP ART UNIT: ~~5761~~ 1615
 FILED: April 6, 1999 EXAMINER: Unknown
 INVENTION: "PHARMACEUTICAL CHEWING GUM FORMULATIONS"



Handwritten notes: 1615, 176, 182, 17, 26, 182, 182

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT TRANSMITTAL LETTER

Assistant Commissioner for Patents
 Washington, D.C. 20231

S I R:

Submitted herewith is a Supplemental Information Disclosure Statement for consideration in the above-identified application. This Supplemental Information Disclosure Statement is submitted:

- ☒ Within three months (1) of filing date of a national application; (2) of date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; or (3) before the mailing date of a first Office Action on the merits, whichever occurs last. (No fee is required.)
- ☐ After the mailing date of a first Office Action but before (1) mailing of a final action under 37 C.F.R. §1.113; or (2) mailing of a notice of allowance under §1.311, whichever occurs first.
- ☐ Payment of the fee set forth in 37 C.F.R. §1.17(p) accompanies this submission; or
- ☐ The certification specified in 37 C.F.R. §1.97(e) is made below. (No fee is required.)
- ☐ After the mailing of (1) a final action under 37 C.F.R. §1.113; or (2) notice of allowance under 37 C.F.R. §1.311 whichever occurs first, but before payment of the issue fee. The certification specified in 37 C.F.R. §1.97(e) is made below. The Commissioner hereby is petitioned to consider the Information Disclosure Statement accompanying this submission. Payment for the Petition fee set forth in 37 C.F.R. §1.17(i)(1) accompanies this submission.
- ☐ The undersigned counsel for applicant(s) hereby certifies each item of information identified in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- ☐ The undersigned counsel for applicant(s) hereby certifies that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, or to the knowledge of the undersigned, after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of the statement.
- ☐ A check in the amount of \$_____ to cover any required fee is enclosed.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, by credit any overpayment to Account No. 08-2290. *A duplicate copy of this sheet is enclosed for this purpose.*

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Very respectfully,

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(Reg. No. 30,142)

When phoning re: this application,
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I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 November 23, 1999.

Robert M. Barrett

(Reg. No. 30,142)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

APPLICANT: Ream et al. ATTY DOCKET NO.: P99,0082

SERIAL NO: 09/286,818 GROUP ART UNIT: 1761

FILED: October 20, 1999

INVENTION: "PHARMACEUTICAL CHEWING GUM FORMULATIONS"

Assistant Commissioner for Patents

Washington, D.C. 20231

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In accordance with the provisions of 37 C.F.R. 1.56, Applicants request that a citation and examination of the references identified below and on the attached PTO-1449 form, copies of which are enclosed herewith in accordance with 37 C.F.R. 1.98, be made during the course of examination of the above-mentioned application for United States Patent.

U.S. PATENTS

<u>Patent Number</u>	<u>Inventor</u>	<u>Publication Date</u>
4,154,814	Hand et al.	May 15, 1979
4,400,372	Muhler et al.	August 23, 1983
4,474,749	Kruppa	October 2, 1984
4,563,345	Arrick	January 7, 1986
4,647,450	Peters et al.	March 3, 1987
4,755,389	Jones et al.	July 5, 1988
4,822,597	Faust et al.	April 18, 1989
4,822,816	Markham	April 18, 1989
4,828,820	Glass et al.	May 9, 1989
4,832,994	Fey	May 23, 1989
4,849,227	Cho	July 18, 1989
4,853,212	Faust et al.	August 1, 1989
4,867,989	Silva et al.	September 19, 1989
4,908,211	Paz	March 13, 1990

4,908,212	Kwon et al.	March 13, 1990
4,929,447	Yang	May 29, 1990
4,933,184	Tsuk	June 12, 1990
4,938,963	Parnell	July 3, 1990
4,944,949	Story et al.	July 31, 1990
4,968,716	Markham	November 6, 1990
5,015,464	Strobridge	May 14, 1991
5,070,085	Markham	December 3, 1991
5,124,156	Shibata et al.	June 23, 1992
5,139,787	Broderick et al.	August 18, 1992
5,154,927	Song et al.	October 13, 1992
5,156,842	Mulligan	October 20, 1992
5,179,122	Greene et al.	January 12, 1993
5,182,099	Jonsson et al.	January 26, 1993
5,284,657	Lu et al.	February 8, 1994
5,294,449	Greenberg	March 15, 1994
5,340,566	Curtis et al.	August 23, 1994
5,378,131	Greenberg	January 3, 1995
5,380,530	Hill	January 10, 1995
5,380,535	Geyer et al.	January 10, 1995
5,410,028	Asami et al.	April 25, 1995
5,445,834	Burger et al.	August 29, 1995
5,455,286	Amidon et al.	October 3, 1995
5,488,962	Perfetti	February 6, 1996
5,496,541	Cutler	March 5, 1996
5,512,306	Carlsson et al.	April 30, 1996
5,534,272	Bernstein	July 9, 1996
5,554,380	Cuca et al.	September 10, 1996
5,571,528	Lee et al.	November 5, 1996
5,585,110	Kalili et al.	December 17, 1996
5,593,685	Bye et al.	January 14, 1997
5,605,698	Ueno	February 25, 1997
5,618,517	Miskewitz	April 8, 1997
5,628,986	Sanker et al.	May 13, 1997
5,629,035	Miskewitz	May 13, 1997
5,645,853	Winston et al.	July 8, 1997
5,665,386	Benet et al.	September 9, 1997
5,667,802	Grimberg	December 16, 1997
5,693,334	Miskewitz	December 2, 1997

5,698,215	Kalili et al.	December 16, 1997
5,702,687	Miskewitz	December 30, 1997
5,716,928	Benet et al.	February 10, 1998
5,736,175	Cea et al.	April 7, 1998
5,744,164	Chauffard et al.	April 28, 1998
5,753,255	Chavkin et al.	May 19, 1998
5,756,074	Ascione et al.	May 26, 1998
5,824,291	Howard	October 20, 1998
5,866,179	Testa	February 2, 1999
5,882,702	Abdel-Malik et al.	March 16, 1999
5,900,230	Cutler	May 4, 1999
5,912,030	Huziinec et al.	June 15, 1999
5,922,346	Hersh	July 13, 1999
5,958,380	Winston et al.	September 28, 1999
5,958,472	Robinson et al.	September 28, 1999

FOREIGN PATENTS

<u>Patent Number</u>	<u>Country</u>	<u>Publication Date</u>
84/02271	PCT	June 21, 1984
90/12583	PCT	November 1, 1990
92/06680	PCT	April 30, 1992
2,706,771	France	June 21, 1993

OTHER DOCUMENTS

Akitoshi et al., Abstract "Acceleration of Transdermal Absorption of Pharmaceuticals by Essential Oils and Organic Solvents," Chem. Abst., 112:125228t, 1990.

Bradford, A Rapid and Sensitive Method for the Quantification of Microgram Quantities of Protein Utilizing the Principle of Protein-Dye Binding, Analytical Biochemistry, 72:248-254 (1976).

Nielsen et al., P-Glycoprotein as Multidrug Transporter: A Critical Review of Current Multidrug Resistant Cell Lines, Chimica et Biophysica Acta., 1139:169-183 (1992).

Adams, M.W., d-Alpha Tocopheryl Polyethylene glycol 1000 Succinate (Eastman vitamin E TPGS) as an Emulsifier and Bioenhancer for Drugs and Lipophilic

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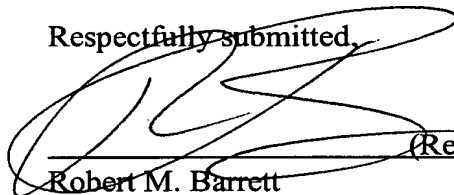
Compounds, 6th International Conference on Pharmaceutical Technology, Paris, 2-4 June, 1992.

- Chang, Tammy et al., "The Effect of Water-Soluble Vitamin E on Cyclosporine Pharmacokinetics in Healthy Volunteers," Abstract in American Society to Clinical Pharmacology and Therapeutics, 57(2):163, Feb. 1995.
- Hebert, Mary F. et al.; "Bioavailability of Cyclosporine with Concomitant Rifampin Administration is Markedly Less Than Predicted by Hepatic Enzyme Induction" (1992) *Clin. Pharmacol. Ther.* 52:453-457.
- Kronbach, Thomas et al.; "Oxidation of Midazolam and Triazolam by Human Liver Cytochrome P450IIIA4" (1989) *Molec. Pharm.* 36:89-96.
- Lalka et al.; "The Hepatic First-Pass Metabolism of Problematic Drugs" (1993) *J. Clin. Pharmacol.* 33:657-669.
- Lum et al.; "Clinical Trials of Modulation of Multidrug Resistance. Pharmacokinetic and Pharmacodynamic Considerations" (1993) *Cancer* 72:3502-3514.
- Muranishi, Shozo; "Absorption Enhancers" (1990) *Crit. Rev. Ther. Drug Carrier Sys.*, 7:1-33.
- Somberg et al.; "The Clinical Implications of First-Pass Metabolism: Treatment Strategies for the 1990's" (1993) *J. Clin. Pharmacol.* 33:670-673.
- Tam, Yun K.; "Individual Variation in First-Pass Metabolism" (1993) *Clin. Pharmacokinet.* 25:300-328.
- Van Hoogdalem et al.; "Intestinal Drug Absorption Enhancement: An Overview" (1989) *Pharmacol. Ther.* 44:407-443.
- Warren et al.; "Increased Accumulation of Drugs in Multidrug-Resistant Cell Induced by Liposomes" (1992) *Cancer Research* 52:3241-3245.
- Watkins, Paul B.; "The Role of Cytochromes P-450 in Cyclosporine Metabolism" (1990) *J. Am. Acad. Dermatol.* 23:1301-1309.
- Wrighton et al.; "In Vitro Methods for Assessing Human Hepatic Drug Metabolism: Their Use in Drug Development" (1993) 25:453-484.
- Wu et al.; "Use of IV and Oral Drug Levels from Cyclosporine (CsA) with Concomitant Rifampin to Differentiate Gut Absorption and Metabolism" (1993) *Pharm. Res.* 10:abstract ppdm8185.

Zamora et al.; "Physical-Chemical Properties Shared by Compounds that Modulate Multidrug Resistance in Human Loukemic Cells" (1988) *Molec. Pharmacol.* 33:454-462.

Applicants look forward to early and favorable consideration of this matter.

Respectfully submitted,



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CERTIFICATE OF MAILING

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